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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
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09/234,532 01/21/99 SAPSE

A 1398-002

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HM12/0302

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|----------|
| EXAMINER |
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OWENS JR., H

| ART UNIT | PAPER NUMBER |
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1623

DATE MAILED:

03/02/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

# Office Action Summary

Application No.  
09/234,532

Applicant(s)  
Sapse

Examiner  
Howard Owens

Group Art Unit  
1623



☐ Responsive to communication(s) filed on \_\_\_\_\_.

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claims

☒ Claim(s) 1-3, 5-7, 9-11, 13-15, and 17-20 is/are pending in the application.

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☒ Claim(s) 1-3, 5-7, 9-11, 13-15, and 17-20 is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been  
☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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***Response to Arguments***

5 The following is in response to the amendment filed 12/3/99:

Claims 4, 8, 12 and 16 have been canceled by applicant.

10 An action on the merits of claims 1-3, 5-7, 9-11, 13-15, 17-20 is contained herein below.

**35 U.S.C. 112**

15 Claims 1-20 rejected under 35 U.S.C. 112(1) are maintained for the reasons of record.

20 Claim 6 rejected under 35 U.S.C. 112(2) is maintained for the reasons of record. Accordingly, dependent claim 9 is rejected as it fails to obviate the rejections set forth in the parent claim(s).

**35 U.S.C. 102**

25 Claims 1, 2 and 4 rejected under 35 U.S.C. 102(b) have been overcome through applicant's amendment.

30 **35 U.S.C. 103**

Applicant's arguments filed in response to the rejection of claims 3 and 6-20 rejected under 35 U.S.C. 103(a), have been fully considered but they are not persuasive. The rejection of claims  
35 3, 6, 7, 9-11, 13-15, 17-20 under 35 U.S.C. 103(a) is maintained for the reasons set forth below. Claims 1, 2 and 5 are newly rejected under 35 U.S.C. 103.

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The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

5 A patent may not be obtained though the invention is not  
identically disclosed or described as set forth in section  
102 of this title, if the differences between the subject  
matter sought to be patented and the prior art are such that  
10 the subject matter as a whole would have been obvious at the  
time the invention was made to a person having ordinary  
skill in the art to which said subject matter pertains.  
Patentability shall not be negated by the manner in which  
the invention was made.

15 Subject matter developed by another person, which qualifies  
as prior art only under subsection (f) or (g) of section 102  
of this title, shall not preclude patentability under this  
section where the subject matter and the claimed invention  
were, at the time the invention was made, owned by the same  
20 person or subject to an obligation of assignment to the same  
person.

Claims 1-3, 5-7, 9-11, 13-15, 17-20 are rejected under 35  
U.S.C. § 103 as being unpatentable over Devita et al., AIDS, 4th  
25 edition, pp. 501-504, in combination with Beale, U.S. Patent No.  
5,756,469 and Lemay et al., Int. Conf. AIDS, vol.5, 1989.

Claims 1-3 is drawn to a composition comprising at least two  
anti-HIV drugs and a cortisol blocker.

30 Claim 5-7, 9-11, 13-15, 17-20 are drawn to a method for the  
management of side effects associated with the administration of  
anti-HIV drug therapy comprising administration to a patient a  
therapeutically effective amount of at least one cortisol  
blocker.

35 Beale teaches the use of anti-cortisol compounds such as  
HMB, DHEA, Ipriflavone and phosphatidylserine in the treatment of  
patients with AIDS to reduce the catabolic effects associated

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with AIDS (col.2-col.8, line 19). Beale does not explicitly teach the use of anti-cortisol compounds in a composition with anti-HIV drugs.

Lemay et al. teach the cortisol blocker ketaconazole in combination with the anti- HIV drug Zidovudine (AZT).

Devita et al. teach that combinations of anti-HIV drugs are beneficial in treating HIV infection for several reasons: Two or more drugs may have additive or synergistic interactions that produce better efficacy than with either drug alone, lower doses than those employed in monotherapies- possibly decreasing toxicity, delaying the emergence of a resistant virus that can escape drug inhibition, and targeting of different cellular and tissue reservoirs of the virus; particularly AZT in combination with ddC, ddI or 3TC as the combination of AZT with these agents present stronger synergy over monotherapies or treatment of AZT resistant isolates (DeVita et al., AIDS, 4th edition, pp. 502-504).

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

A *prima facie* case of obviousness is supported when the prior art alone would have appeared to suggest doing, at the time

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the invention was made, what the applicant has done. It would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made that a cortisol blocker could be used in a composition with an anti-HIV drug.

5           One of skill in the art would have been provided with a clear motivation and a reasonable expectation of success to combine the teachings of Beale with that of Lemay and Devita given that any method of treatment would seek to reduce the catabolic effects associated therein, as Lemay and Devita  
10       teach the benefits of combination therapies wherein cortisol blockers are used in the treatment of HIV to increase the synergistic effects of an anti-HIV drug and cortisol blockers are shown by Beale to reduce the catabolic effects of the disease itself, whether the catabolic effects are  
15       associated with the use of the anti-HIV drug or the disease itself, one of skill would include cortisol blockers in the treatment regime to reduce or alleviate these catabolic effects as an adjunct to a combination therapy.

20           In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231  
25       USPQ 375 (Fed. Cir. 1986). The examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally  
30       available to one of ordinary skill in the art. See *In re Fine*,

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837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). The prior art need not explicitly state each side effect, only provide a motivation to combine the two compounds, in this case, applicant's side effects would be viewed as catabolic effects, and given that Lemay and Devita teach the benefits of combination therapies wherein cortisol blockers are used in the treatment of HIV to increase the synergistic effects of an anti-HIV drug and cortisol blockers are shown by Beale to reduce the catabolic effects of the disease itself, whether the catabolic effects are associated with the use of the anti-HIV drug or the disease itself, one of skill would include cortisol blockers in the treatment regime to reduce or alleviate these catabolic effects as an adjunct to a combination therapy.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CAR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CAR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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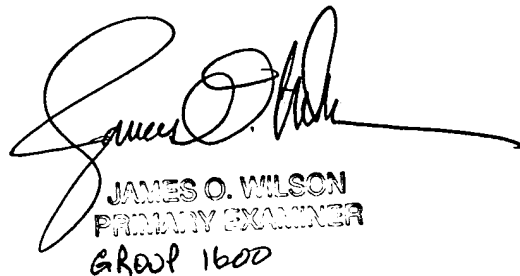
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Howard Owens whose telephone number is (703) 306-4538 . The examiner can normally be reached on Mon.-Fri. from 8:30 a.m. to 5 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the Primary Examiner signing this action, James O. Wilson can be reached on (703) 308-4624 . The fax phone number for this Group is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

Howard Owens  
Group 1623



JAMES O. WILSON  
PRIMARY EXAMINER  
GROUP 1600